K 043385

510(k) SUMMARY

APR 1 2 2005

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Genzyme Corporation is providing a summary of the safety and effectiveness information available for the OSOM hCG Combo test.

1. Sponsor/Applicant Name and Address:

   Genzyme Corporation
   500 Kendall Street
   Cambridge, MA 02142

2. Sponsor Contact Information:

   E.V. Goorchenko
   Director of Regulatory Affairs
   Phone: 858/777-2614
   FAX: 858/452-3258
   Email: Gene.Goorchenko@genzyme.com

3. Date of Preparation of 510(k) Summary:
   February 22, 2005

4. Device Trade or Proprietary Name:

   OSOM hCG ComboTest

5. Device Common/Usual or Classification Name:

   hCG Test System

6. Legally Marketed Devices to which Equivalence is Being Claimed:

Quidel QuickVue®+ One-Step hCG Combo Test (K)

7. Device Description

Intended Use

The Genzyme Diagnostics OSOM hCG Combo test is a rapid immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum as an aid in the early detection of pregnancy. This test is for use in physicians' offices and clinical laboratories.

Principle of the Device

The OSOM hCG Combo device is a solid phase, sandwich-format immunochromatographic assay for the qualitative detection of hCG. Urine or serum is added to the sample well of the test device using the fixed volume Pipette® provided. The sample migrates through reaction pads where hCG, if present in the sample, binds to a monoclonal anti-hCG dye conjugate. The sample then migrates across a membrane towards the results window, where the labeled hCG complex is captured at a test line region containing immobilized rabbit anti-α hCG. Excess conjugate will flow past the test line region and be captured at a control line region containing an immobilized antibody directed against the anti-hCG dye conjugate (with or without hCG complexed to it).

The appearance of two gray or black bands in the results window indicates the presence of hCG in the sample. If a detectable level of the hCG is not present, only the control band will appear in the results window.

8. Comparison of Technological Characteristics of OSOM hCG Combo with Legally Marketed Device:

The similarities with, and differences between, the OSOM hCG Combo test and the Quidel QuickVue®+ One-Step device are described in Table 1.

9. Agreement with Predicate Device:

A total of 634 urine samples and 691 serum samples were tested and compared to the results obtained with a currently marketed qualitative hCG assay. The agreement for the OSOM urine procedure, on both positive and negative samples, was >99% and, for the OSOM serum procedure, agreement on both positive and negative samples was >99%.

Table 1. Summary of Device Similarities and Differences

	Genzyme OSOM hCG Combo Test	**Quidel QuickVue®+ hCG-Combo Test**
Assay Format	Lateral flow immunoassay	Lateral flow immunoassay
Result Format	Visible lines: Negative=one gray or black Control Line Positive=one gray or black Control Line and one gray or black Test Line	Visible lines: Negative =two blue lines Positive = one pink line and two blue lines.
Specimen	Urine or Serum	Urine or Serum
Antibodies	Mouse monoclonal and rabbit polyclonal	Mouse monoclonal and goat polyclonal

Internal Control	Yes	Yes
Time To Result	Urine: Read result at 3 minutes Serum: Read result at 5 minutes	Urine: Read result at 3 minutes Serum: Read result at 5 minutes
Analytical Sensitivity	Urine: 20 mIU/mL Serum: 10 mIU/mL	Urine: 20 mIU/mL Serum: 10 mIU/mL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 1 2 2005

Gene Goorchenko
Director of Regulatory Affairs
Genzyme Diagnostics
6659 Top Gun Street
San Diego, CA 92121

Re: k043385
Trade/Device Name: OSOM hCG Combo
Regulation Number: 21 CFR 862.1155
Regulation Name: Urinary pH (nonquantitative) test system
Regulatory Class: Class II
Product Code: JHI
Dated: March 18, 2005
Received: March 21, 2005

Dear Mr. Goorchenko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K043385

Device Name: OSOM hCG Combo

Indications for Use: The OSOM hCG Combo test is a rapid immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum as an aid in the early detection of pregnancy. This test is for use in physicians' offices and clinical laboratories.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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